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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|---------------|----------------------|-------------------------|-----------------|
| 09/834,434 04/13/2001 | | Mark A. Emalfarb | 3123-4006 | 5903 |
| 75 | 90 05/21/2003 | | | |
| Eugene Moroz MORGAN & FINNEGAN, L.L.P. 345 Park Avenue | | | EXAMINER | |
| | | | WESSENDORF, TERESA D | |
| New York, NY 10154-0053 | | | ART UNIT | PAPER NUMBER |
| | • | | 1639 | lo |
| | | | DATE MAILED: 05/21/2003 | 10 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|---|--|--|--|--|--|
| Office Action Summary | | | | | | | |
| | | 09/834,434 | EMALFARB ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| <u> </u> | he MAILING DATE of this communicati | T. D. Wessendorf | the correspondence address | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| THE MA - Extension after SIX - If the per - If NO per - Failure to - Any reply | TENED STATUTORY PERIOD FOR I ILING DATE OF THIS COMMUNICAT as of time may be available under the provisions of 37-(6) MONTHS from the mailing date of this communicated for reply specified above is less than thirty (30) day lod for reply is specified above, the maximum statutory reply within the set or extended period for reply will, by received by the Office later than three months after that term adjustment. See 37 CFR 1.704(b). | TION. CFR 1.136(a). In no event, however, may a repliction. s, a reply within the statutory minimum of thirty (3 y period will apply and will expire SIX (6) MONTH by statute. cause the application to become ABAN | y be timely filed 30) days will be considered timely. S from the mailing date of this communication. IDONED (35 U.S.C. 6 133) | | | | |
| 1)⊠ R | esponsive to communication(s) filed o | n <u>13 March 2003</u> . | | | | | |
| | | This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition | | | | | | | |
| | aim(s) 1-48 is/are pending in the appli | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. | | | | | | |
| 6)☐ Claim(s) is/are rejected. | | | | | | | |
| | 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 1-48 are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a)□ <i>A</i> | ll b)☐ Some * c)☐ None of: | | | | | | |
| 1.[| _ | | | | | | |
| _ | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) 🔲 Notice of I | References Cited (PTO-892) Draftsperson's Patent Drawing Review (PTO-94 n Disclosure Statement(s) (PTO-1449) Paper N | 8) 5) Notice of Infor | nmary (PTO-413) Paper No(s) mal Patent Application (PTO-152) . | | | | |
| Patent and Tradema | ork Office | | Title 1400 Comments | | | | |

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DETAILED ACTION

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 and 9, drawn to a method of expressing and screening a plurality of proteins.
- II. Claims 3-5 and 10-12, drawn to a method of producing.
- III. Claim 6 and 13 drawn to a method of screening a plurality of monoclonal fungal cultures for a metabolite.
- IV. Claims 7-8 and 14-15 drawn to a method of optimizing a protein's activity.
- V. Claim 44, drawn to a method for obtaining a protein.
- VI. Claim 45, drawn to a method of obtaining a protein with an optimized activity or property of interest.
- VII. Claim 46, drawn to a method of making a library of transformed filamentous fungi.
- VIII. Claim 47, drawn to a library of transformed fungi.
- IX. Claim 48, drawn to a method for obtaining a transformed fungal host.

Claims 16-43 would be examined with any one of the elected Groups I-IV.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with different modes of operation having different steps with different functions and/or effects or results.

Inventions 1-IV and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be obtained by the different process steps. Also, the product can be obtained using other host organism, vectors and other recombinant components.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-IX,

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specifically the literature searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

. If Groups I-IV is elected, applicants are to elect a single species from the following:

- A). Culture viscosity as recited in claims 16-19.
- B). A single species of the protein encoded by a signal sequence recited in claim 21.
- C). A species of fungus (not the generic as recited in claim 29. Rather a single species as recited in example claims 31-34).
- D. A single biomass ratio as recited in any one of claims 36-38.
 - E. A single transferable reproductive elements.

Each of the species recited in the subgroups A-E differs, if not in structure, in function and/or modes of operation. A prior art reference anticipating one would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the

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claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 6 and 7 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

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admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be

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reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf Primary Examiner Art Unit 1639 Page 7

tdw May 19, 2003